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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/080,390	02/25/2002	Marc S. Hermelin	24016-A	9541

7590

07/22/2003

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EXAMINER

LEVY, NEIL S

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 07/22/2003

7

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

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Application No. 080390

Applicant(s) HERMEYN et al

Examiner MBT/ley

Group Art. Unit 1616

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—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

## P r i d f r Reply

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A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

6/23/83

- ☒ Responsive to communication(s) filed on
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 38-68 is/are pending in the application.
- Of the above claim(s) 61-65 is/are withdrawn from consideration.
- ☐ Claim(s) is/are allowed.
- ☒ Claim(s) 38-60, 66-68 is/are rejected.
- ☐ Claim(s) is/are objected to.
- ☒ Claim(s) 38-68 are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number)
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received:

## Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s).
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other

Office Action Summary

Applicant's election with traverse of group I species mammal, therapeutics, cardiovascular agents in Paper No. 6 is acknowledged. The traversal is on the ground(s) that overlapping subject matter would not pose a serious burden and elected species are merely examples. This is not found persuasive because in fact a serious burden of search and examination exists, and species, not declared equivalent, also pose a serious search burden.

The requirement is still deemed proper and is therefore made FINAL.

Claims 64, 65, 61-63 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 6.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 38-60, 66, 67, 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hsiao et al 4,863,743 in view of Myers et al 5,567,439 and Paradissis – 4,764,375.

The instant claims are silent as to the Flavoring agent, animal, particles, and extended release coating. Hsiao can be construed as meeting them, with the sugar, used in coated prior art tablets (col. 7, last paragraph, top, and col. (8), if flavor is deemed a parameter of concern. In all other respects,

Hsiao provides coated Kcl (Example 1) granules, with microcrystalline cellulose and crospovidone, PEG, as tablets, Example 2, adds magnesium stearate; similar to applicants Na-stearyl fumarate of Example 1; the tablets are the instant formulations of 20m Eq of Kcl. However 68%-86% Kcl is shown (column 7). Disintegration occurs within 5 minutes (column 5, lines 19-24) with sustained release leading to 90% Kcl released after 6 hours (Tables I, II).

The components providing for the dispersing and releases periods as instantly claimed are thus shown by Hsiao.

Administration as a liquid was seen as placing in water, or on an aqueous food, which is then administered to those having swallowing difficulties (col. 5) line 65 – line 7, col. 6). ~~String~~ and Mixing if desired, is known – it was used in preparation (Example 2) thus would be within the purview of one to perform, if the desired dissolution period was shorter than produced by simply placing in water. This is the instant invention, absent clear showing of a colorant and flavorant. Paradissis is evidence it was well know at the time of the instant invention, to add colorants and flavorants even to taste-mask~~ed~~ coated actives (col. 2), including Kcl (claim 7), for particle dispersion in liquids. Further, multi substance preparations are also known (col. 2, lines 35, 36).

Myers discloses examples of Flavorants (col. 9, top through line 7, col. 10, and colorants (col. 10, lines 28-33), useful in drug tablet (col. 7, lines 47-49) compositions.

It would have been obvious to a person of ordinary skill in the art at the time invention was made, desiring to utilize Hsiao's Kcl tablet in a form to provide enhanced

palatability, dispensability and sustained release, as taught by paradissis and exemplified by Myers.

All the critical elements of the instant are disclosed. The amounts, dosage regiments and mixing times are result effective parameters chosen to obtain the desired effects. It would be obvious to vary the ingredients to optimize the effect desired, depending upon the intended active agent, concern for side effects, species, age, sex, dosage, minimization of number of applications, patient acceptance for example.

The instant invention provides well-known old art recognized effects, applied by well known art-recognized methods to achieve the desired effects.

Applicant has not provided any objective evidence of criticality, nonobvious or unexpected results that administration methods with the particular ingredients' or dispersion times provides any greater or different level of prior art expectation as claimed, and the use of ingredient for the functionality for which they are known to be used is not basis for patentability.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Neil Levy whose telephone number is (703) 308-2412. The examiner can normally be reached on Tuesday through Friday 7 AM to 5:30 Pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 872-9307 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

A handwritten signature in black ink, appearing to read "Neil S. Levy". The signature is fluid and cursive, with the first name "Neil" being more prominent than the last name "Levy".

Levy/LR  
July 16, 2003

NEIL S. LEVY  
PRIMARY EXAMINER